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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 12

Serial Number: 08/399,404
Filing Date: 3/6/95
Appellant: Stewart D. Lyman

Elizabeth Hurley
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's Brief on appeal, filed 2/23/98 (Paper No. 10).

The text of those sections of Title 35 U.S.Code not included in this appeal can be found in a previous Office action herein.

(1) **Real Party of Interest.**

A statement identifying the real party of interest in contained in the Brief.

(2) **Related Appeals and Interferences Identified.**

A statement identifying that no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the Brief.

(3) **Status of Claims.**

The statement on the status of claims contained in the Brief is correct.

Claims 1-7, 9 and 10 are rejected under 35 U.S.C. § 103.

(4) **Status of Amendments After Final.**

Appellant's statement of the status of amendments after final rejection contained in the Brief is correct. No amendment was filed subsequent to the final Office Action.

(5) **Summary of Invention.**

The summary of invention contained in the Brief is correct.

(6) **Issues.**

Appellant's statement of the sole issue in the Brief is correct.

(7) **Grouping of Claims.**

Appellant's Brief includes a statement that claim 5, if written as an independent claim, would be separately patentable. Appellant's reasons set forth in 37 CFR 1.192(c)(7) and (c)(8) and the examiner's rebuttal are set forth below.

(8) **Claims Appealed.**

The copy of the appealed claims contained in the Appendix to the Brief is correct.

However, it is noted that in claim 1(e), line 3 that the word "and" after the phrase "selecting means" should be deleted for clarity.

(9) **Prior Art of Record.**

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

A) Gillis, U.S. Patent No. 5,199,942.
B) Heimfeld et al., WO 930826.
C) Lyman, EP 0627487.
D) Lyman et al., Cell 75: 1157-1167 (1993).
E) Stewart et al., Blood 81: 2283-2289 (1993).

(10) Grounds of Rejection.

The following ground(s) of rejection are applicable to the appealed claims.

Rejection Under 35 U.S.C. § 103

Claims 1-7, 9 and 10 are rejected under 35 U.S.C. § 103 as being unpatentable over Heimfeld et al. (WO 93/0826) in view of Gillis (U.S. Patent No.5,199,942.), Lyman (Cell, 1993) or Lyman et al. (EP 0627487) and in further view of Stewart et al. (Blood, 1993). The instant claims are drawn to the use of an flt3-ligand as a cytokine or a flt3-ligand receptor binding protein in combination with other growth factors and further with anti-metabolites in the selection of hemopoietic stem or progenitor cells.

Heimfeld et al. teach methods of isolating (including the CD34 specificity) and expanding (including CSF, GM-CSF, IL-3, IL-6, SF growth factors) human hemopoietic stem cells for bone marrow transplantation. Heimfeld et al. differs from the instant claims by not reciting the ECCAT kit per se, by not reciting flt-3 ligand, IL-1α and GM-CSF/IL-3 fusion proteins (as growth factors) or flt3-ligand binding proteins or 5-fluorouracil anti-metabolite in the selection of primitive hemopoietic stem cells. However, Heimfeld et al. does provide the art known teaching of affinity reagents for selecting hemopoietic stem and progenitor cells (means for isolating selected cells), means for incubating isolated cells, cellular growth media and combining growth factors to isolate and expand hemopoietic stem and progenitor cells (see entire document) at the time the invention was made. No positive recitation of the ingredients other than certain reagents (e.g. flt-3 ligand, flt3-ligand binding proteins, IL-1α , GM-CSF/IL-3 fusion proteins and anti-metabolites) and the claimed recitation of an extracorporeal cell culture and transplantation kit distinguishes this reference over the instant claims. The use of alternative growth factors or regents to isolate, select and expand hemopoietic cells was known in the prior art, as taught by Gillis (U.S. Patent No.5,199,942.), Lyman (Cell, 1993) or Lyman et al. (EP 0627487A2) and in further view of Stewart et al. (Blood, 1993). It was known that such cells were useful for reconstituting the immune and hemopoietic systems via transplantation of hemopoietic stem and progenitor cells and for gene therapy protocols, also taught by the references of record (for example, see Summary of the Inventions or Abstracts/Discussions).

Lyman et al. (Cell, 1993) teach the flt3-ligand as a growth factor for primitive hemopoietic stem cells as well as the ability of flt3-Fc to bind flt3-ligand (see entire document). The addition of stem cell factor to flt3-ligand provides a stronger response to stem cells.

Lyman et al. (EP 0627487) teach the use of flt3-ligand as a cytokine to stimulate hemopoietic stem and progenitor cells as well as flt3-ligand binding proteins as affinity reagents for purifying stem cells (see entire document).

Gillis et al. also teaches the use of combinations of cytokines including the use of IL-1α and GM-CSF/IL-3 fusion proteins in the expansion of human hemopoietic stem cells.

Stewart et al. the known use of the 5-fluorouracil anti-metabolite in the selection of primitive hemopoietic stem cells with high proliferative potential and associated rapid marrow recovery. Therefore, the ordinary artisan would have been motivated to select primitive human hemopoietic stem cells with anti-metabolites such as 5-fluorouracil to provide for cells with high proliferative potential and associated rapid hemopoietic recovery.

One of ordinary skill in the art at the time the invention was made would have been motivated to select primitive human hemopoietic stem cells with various means to isolate said primitive hemopoietic stem cells, including CD34 and flt3-ligand binding proteins as affinity reagents and/or anti-metabolites in the selection of hemopoietic stem cells with high proliferative and pluripotent potential as well as the use of flt3-ligand in combination with other growth factors/cytokines in the expansion of hemopoietic stem cells to treat human diseases in the need of hemopoietic repopulation. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

(11) Response to Argument

Rejection Under 35 U.S.C. § 103

Appellant's arguments have been fully considered but are not found convincing essentially for the reasons of record set forth in Paper Nos. 4 and 7.

Appellant argues that the rejection is based on the notion that the claimed invention is a combination and since elements found in the combination made by appellant can be found in various prior art references, appellant's combination was obvious at the time the it was made. Appellant further argues that there must be some suggestion of motivation in the prior art to make the claimed invention and that obviousness must be determined with respect to the invention as a whole.

Appellant argues that a claimed combination is obvious when made only when there existed some suggestion or motivation in the prior art to make the particular combination claimed. Here, appellant argues that none of the references describe an ESCCAT kit, provide a suggestion or motivation to make the combination made by appellant, i.e. a kit for the ex vivo expansion of cells by exposure to flt3-ligand and another growth factor. Appellant asserts that not one of the cited references recites a kit, therefore a kit cannot be encompassed by the combination of references. Appellant asserts that while a kit for selection, isolation, and expansion of populations of cells might be convenient and economical, that a particular combination of elements is conventional and economical does not without more, render the combination obvious. Appellant argues that one cannot use hindsight reconstruction to pick and choose among the isolated disclosure in the prior art to deprecate the claimed invention, and, in turn, that the rejection of record pieced appellant's invention together.

With respect to claim 5, appellant argues that the final Office Action did not discuss the antimetabolite limitation of claim 5. However appellant acknowledges the intention of the references of record to encompass claim 5 as well and that the instant claims were rejected in view of the prior art of record. Appellant acknowledges Stewart et al.'s disclosure of the use of 5-fluorouracil antimetabolite in the selection of primitive hematopoietic stem cells with high proliferative potential and associated rapid marrow recovery (Blood, 1993). Appellant argues that even if one would have been motivated to use antimetabolite exposure as a cell selection technique, no reasoning as to what would motivate one to use antimetabolite exposure and either SF or flt3-ligand, as a cell selection technique in appellant's invention, i.e. a kit for isolation and expansion of selected cells. Finally, appellant argues that simply because cell expansion techniques and the use of anti-metabolites to select particular populations of cells existed in the prior art does not mean that there was any suggestion to combine these elements in a novel kit format.

In contrast to appellant's arguments, the following is noted. The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. See MPEP 2144. In considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. In re Preda, 159 USPQ 342, 344 (CCPA 1968). See MPEP 2144.01. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose . . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven , 205 USPQ 1069, 1072 (CCPA 1980) . See MPEP 2144.06. The motivation to combine [prior art references] can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. See MPEP 2144.07. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 170 USPQ 209 (CCPA 1971) See MPEP 2145.

Applicant's arguments appear to focus on the lack of a recitation for a kit in the prior art, said kit being a combination of elements taught in the prior art. The combined teachings of the prior art teach the use of various elements in the selection of hemopoietic stem cells and the expansion of hemopoietic cells; therefore the teachings are drawn to a common purpose. As appellant acknowledges, the combination of the prior art teaches the claimed elements of the kit and their use in various protocols, including the same purposes as disclosed in the instant application. While the claim recites a kit, no positive recitation of the ingredients distinguishes it over the references; therefore the kit is encompassed by the references. However, if this is not the case, it was a well known convention in the art to place these components in a pack for convenience and economy. In the absence of any recitation in the claims or any direction in the specification to the contrary, the recitation of kit reads on component parts capable of being assembled or a plurality of elements grouped together as a kit. Therefore, the prior art teaches all of the elements of the claims for the same purposes and, in turn, meet the claimed extracorporeal cell culture and transplantation kit, encompassed by the claimed invention.

In contrast to appellant's assertions of lack of motivation and in support of the common purposes taught by the prior art, the following is noted. Heimfeld et al. teaches the methods for selectively expanding stem cells to reconstitute the immune system bone marrow transplantation as well as autologous transplantation (see Background of the Invention and Summary of the Invention). Gillis et al. Teaches selecting and expanding hemopoietic progenitor cells for autologous progenitor cell transplantation (see Summary of the Invention). Lyman et al. (EP) teaches the isolation and expansion of hemopoietic progenitor or stem cells for transplantation procedures as well as to be transfected for use in gene therapy (see Summary of the Invention).

In addition and with respect to claim 5 and the use of anti-metabolites, Stewart et al. teaches the isolation and expansion of hemopoietic stem and progenitor cells for transplantation and for gene insertion in gene therapy protocols (see Abstract). Also, Stewart et al. teaches the use of 5-fluorouracil in other schedules or in other agents in strategies to further enhance stem or progenitor cell generation and improve recovery (see Discussion, particularly page 2288, column 1, paragraph 3). This reference also employs the use of known cytokines including those encompassed by the claimed invention and taught above in clonal assays to test and expand cells derived from 5-fluorouracil-treated cell sources (see entire document, including Clonogenic Assays and Discussion).

Therefore, the prior art including those encompassing claim 5 and the use of anti-metabolites teach the very same purposes as disclosed in the specification. For example, page 3, paragraph 4 of the Summary of the Invention discloses that the kits according to the invention are useful for selecting and expanding hemopoietic stem or progenitor cell expansion and transplantation and gene therapy.

Appellant's arguments are not found persuasive.

(12) For the above reasons, it is believed that the rejections should be sustained.

Respectively submitted,

Lila Feisee
Supervisory Primary Examiner

LILA FEISEE
SUPERVISORY PATENT EXAMINER

Phillip Gambel, PhD
Patent Examiner
Technology Center 1600
Art Unit 1642
May 13, 1998

Argument

Claims 1, 4, 6, 7, 9 and 10 are not *prima facie* obviousness over the prior art

In the final Office Action, the Examiner rejected claims 1, 4, 6, 7, 9 and 10 under 35 U.S.C. 103 as being unpatentable over Heimfeld et al. (WO 93/0826) in view of Lyman (Cell 1993) or Lyman et al. (EP 0627487A2), Stewart et al. (Blood, 1993) and Gillis et al. (U.S. Patent No. 5,199,942). The Examiner has asserted that "Heimfeld et al. teach methods of isolating (including CD34) and expanding (including CSF, GM-CSF, IL-3, IL-6, SF) human hemopoietic stem cells for bone marrow transplantation." See the first Office Action (Paper No. 4) at page 3, paragraph 20. Additionally, the Examiner has stated that Lyman (Cell 1993) teaches the flt3-ligand as a growth factor for primitive hematopoietic cells, and that Lyman (EP 0627487A2) teaches the use of flt3-ligand as a cytokine to stimulate hematopoietic stem and progenitor cells. See the first Office Action (Paper No. 4) at page 5, paragraph 23. Regarding Stewart, the Examiner has stated that the reference teaches the use of the 5-fluorouracil antimetabolite in the selection of primitive hematopoietic stem cells. See the first Office Action (Paper No. 4) at page 4, paragraph 22. The Examiner has further asserted that Gillis teaches the use of combinations of cytokines, including IL-1α and GM-CSF/IL-3 fusion proteins, in the expansion of human hematopoietic cells. See the first Office Action (Paper No. 4) at page 4, paragraph 21.

In the amendment filed in response to the first Office Action, Appellant argued that the references cited by the Examiner did not suggest the claimed invention, which is a kit for the *ex vivo* expansion of cells and requires exposure of the cells to both flt3-

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ligand and another growth factor, and therefore the claimed invention was not obvious when made. In response, the Examiner stated that

> Applicant's arguments...have been fully considered but are not found convincing. Applicant's arguments appear to focus on the lack of a recitation for a kit in the prior art, said kit being a combination of elements taught in the prior art. The combined teachings of the prior art teach the use of various elements in the selection of hemopoietic stem cells and the expansion of hemopoietic cells; therefore the teachings are drawn to a common purpose.

See the Office Action dated January 22, 1997 (Paper No. 7), at page 3, paragraph 7. The rejection is thus based on the notion that 1) the claimed invention is a combination, and 2) since elements found in the combination made by Appellant can be found individually in various prior art references, Appellant's combination was obvious at the time it was made. Appellant submits that this analysis is legally erroneous.

Under 35 U.S.C § 103,

> [a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter <u>as a whole</u> would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a)(emphasis added). To establish a *prima facie* case of obviousness, it must be shown that there was some suggestion or motivation in the prior art to make the claimed invention. Furthermore, obviousness must be determined with respect to the invention as a whole. Assessing the claimed invention as a whole "is essential for combination inventions, for generally all combinations are of known elements."

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Interconnect Planning v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985). The Federal Circuit has stated that

> it is irrelevant in determining obviousness that all or all other aspects of the claim may have been well known in the art. Hence the statute, the law established not by judges but by Congress, requires that the invention as claimed be considered "as a whole" when considering whether that invention would have been obvious when it was made.

Jones v. Hardy, 727 F.2d 1524, 1528 (Fed.Cir. 1984) (citations omitted).

Thus, contrary to the assertion of the Examiner, the mere fact that individual elements of a claimed combination are known does not render the specific combination of those elements obvious. A claimed combination is obvious when made only when there existed some suggestion or motivation in the prior art to make the particular combination claimed. *See In re Gordon*, 733 F.2d 900,902 (Fed. Cir. 1984)("The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desireability of the modification.") In this case, it has not been stated how the cited references, none of which describe an ESCCAT kit, provide a suggestion or motivation to make the combination made by Appellant, i.e., a kit for the *ex vivo* expansion of cells by exposure to flt3-ligand and another growth factor.

Regarding Appellant's argument to this effect, made in the amendment dated October 8, 1996, the final Office Action stated only that

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> [w]hile the claim recites a kit, no positive recitation of the ingredients distinguishes it over the references; therefore the pack is encompassed by the references. However, if this is not the case, it was a well known convention in the art to place these components in a pack for convenience and economy.

See the final Office Action at page 3, paragraph 7 (Paper No. 7). Not one of the cited references recites a kit, however, and therefore a kit cannot be encompassed by the combination of those references. Moreover, while a kit for selection, isolation and expansion of populations of cells might be convenient and economical, that a particular combination of elements is convenient and economical does not, without more, render that combination obvious.

In *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, the Federal Circuit, in affirming a decision of nonobviousness, stated that

> the references in combination do not suggest the invention as a whole claimed in the '027 patent. Absent such a suggestion to combine the references, respondents can do no more than piece the invention together using the patented invention as a template. Such hindsight reasoning is impermissible.

988 F.2d 1165, 1178 (Fed. Cir. 1993) (citations omitted). *See also, In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("It is impermissible to use the claimed invention as a 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious") and *In re Fine*, 837 F.2d 1071, 1075 (Fed.Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among the isolated disclosures in the prior art to deprecate the claimed invention"). The Examiner in this case has done exactly what the Federal Circuit has explicitly prohibited, i.e., pieced Appellant's

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invention together using the patented invention as a template. Such an approach is clearly impermissible.

In sum, since it has not been shown that the claimed invention was suggested in the prior art, a *prima facie* case of obviousness has not been established, and the rejection should be reversed.

Claim 5 is not *prima facie* obvious over the prior art

As noted above, no specific grounds for the rejection of claim 5 were given in the detailed action of the final Office Action (nor, in fact, has claim 5 ever been specifically addressed on the record of this case). Nonetheless, in the event that the Examiner intended to reject claim 5 as obvious over the five cited references, the nonobviousness of this claim will be addressed.

Claim 5 is directed to a kit for selecting, isolating and expanding hematopoietic progenitor or stem cells, which become committed to differentiate along certain lineages. The claim depends from claim 1, and contains the additional limitation that the means for selecting the cell population comprises an antimetabolite and a growth factor; either SF or flt3-ligand. The final Office Action did not discuss the antimetabolite limitation of the claim. However, the first Office Action rejected several of the claims over Heimfeld and Stewart, on the basis that Heimfeld taught methods of isolating and expanding cells for bone marrow transplantation, and Stewart disclosed "use of 5-fluorouracil antimetabolite in the selection of primitive hematopoietic stem

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cells with high proliferative potential and associated rapid marrow recovery." See the first Office Action (Paper No. 4) at page 4, paragraph 22.

In making the rejection, the Examiner stated that "one of ordinary skill in the art would have been motivated to select primitive human hematopoietic stem cells with antimetabolites such as 5-fluorouracil." See the first Office Action (Paper No. 4) at page 5, paragraph 22. However, even if one would have been motivated to use antimetabolite exposure as a cell selection technique, the Examiner provides no reasoning as to what would motivate one to use antimetabolite exposure and either SF or flt3-ligand, as a cell selection technique in Appellant's invention, i.e., a kit for isolation and expansion of selected cells.

As discussed above, it is the invention as a whole that must be suggested by the prior art. Moreover, the Examiner is not permitted to use the claimed invention as a template to piece together the prior art. *In re Fritch* at 1226. Simply because cell expansion techniques and the use of antimetabolites to select particular populations of cells existed in the prior art does not mean that there was any suggestion to combine these elements in a novel kit format. Thus, a *prima facie* case of obviousness has not been established with respect to claim 5.

Conclusion

For the reasons detailed above, the Examiner has failed to establish a *prima facie* case of obviousness of the claims over the cited references. Appellant therefore respectfully requests that the rejection of the claims be reversed.

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Appellant notes that in the final Office Action, dated January 22, 1997, the Examiner stated that the declaration submitted with the application is defective, in that the post office address must be supplied. Appellant submits that the address listed in the declaration is the correct post office address, and therefore submission of a supplemental declaration is unnecessary. However, in the event that the Examiner continues to require a supplemental declaration, one will be submitted.

If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Appendix

Claims on Appeal

1. An extracorporeal cell culture and transplantation kit comprising:

(a) means for selecting cells having a desired phenotype in a cell mixture obtained from a human;

(b) means for isolating the selected cells from the mixture;

(c) means for incubating the isolated cells;

(d) a composition comprising an effective amount of flt3-ligand and a growth factor, wherein the growth factor is selected from the group consisting of: GM-CSF, G-CSF, IL-1, IL-3, IL-6, TPO, EPO, SF and a GM-CSF/IL-3 fusion protein; and

(e) cellular growth medium;

wherein the isolating means is adapted to receive the mixture of cells and the selecting means and is adapted to isolate the selected cells from the mixture; and the incubating means is adapted to receive the isolated cells from the isolating means, the cellular growth medium and the composition, and is further adapted to permit contact of the composition with the isolated cells sufficient to permit cellular expansion of the isolated cells.

2. A kit according to claim 1, wherein the isolated cells are human hematopoietic stem or progenitor cells.

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3. A kit according to claim 1, further comprising a container for first containing a mixture of cells collected from a human.

4. A kit according to claim 2, wherein the means for selecting the hematopoietic stem or progenitor cells comprises at least one of a) flt3 receptor binding protein or b) a monoclonal antibody that binds to a cellular marker selected from the group consisting of: CD34 and Thy-1.

5. A kit according to claim 2, wherein the means for selecting the hematopoietic stem or progenitor cells comprises an antimetabolite and a growth factor selected from the group consisting of SF and flt3-ligand.

6. A kit according to claim 1, wherein the growth factor is a GM-CSF/IL-3 fusion protein.

7. A kit according to claim 1, wherein the growth factor is IL-1.

9. A kit according to claim 1, wherein the growth factor is GM-CSF.

10. A kit according to claim 1, wherein the growth factor is IL-3.

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